



Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States

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What's New in the Guidelines

Text and references throughout the guidelines were updated to include new data and publications where relevant. These changes are highlighted in yellow in the PDF version of the guidelines. Major section revisions are summarized below.

April 14, 2020

Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection

- The Panel has changed the term “empiric HIV therapy” to “presumptive HIV therapy” in this section and throughout the guidelines to be consistent with the terminology used by the World Health Organization. The Panel recommends presumptive HIV therapy for infants who are at a higher risk of perinatal HIV acquisition. For clarity, the term “multidrug ARV prophylaxis” has been changed to “two-drug ARV prophylaxis.”
- Table 6. Neonatal Antiretroviral Management According to Risk of HIV Infection in the Newborn and Table 7. Antiretroviral Dosing Recommendations for Newborns have been revised to clarify the ARV regimens and the duration and dosing of ARV drugs that are used for presumptive HIV therapy.
- The two-drug regimen that was used in NICHD-HPTN 040/PACTG 1043 for infants who were at a higher risk of HIV acquisition is no longer included in Tables 6 and 7; this regimen is described in the text instead, see the [Two-Drug Antiretroviral Prophylaxis](#) section.

January 17, 2020

Long-Term Follow-Up of Infants Exposed to Antiretroviral Drugs

The Panel has added new subsections about potential adverse growth and metabolic and neurodevelopmental outcomes of *in utero* HIV and antiretroviral drug exposure.

December 24, 2019

Patient Counseling and Informed Decision-Making

In a number of sections, the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) emphasizes the importance of patient counseling and recommends supporting informed decision-making regarding the use of dolutegravir (DTG) and other antiretroviral (ARV) drugs for women who are pregnant or who are trying to conceive (AIII). A counseling guide has been added to summarize the content that should be discussed with patients; see [Appendix D: Dolutegravir Counseling Guide for Health Care Providers](#). The Panel also recommends that clinicians discuss future reproductive plans and timing with patients as well as the risks and benefits of conceiving on specific ARV medications and contraceptive options to prevent unintended pregnancy (AIII).

Maternal HIV Testing and Identification of Perinatal HIV Exposure

In addition to recommendations for repeat HIV testing in the third trimester, repeat HIV testing at other times during pregnancy should be considered when clinically indicated. For example, repeat testing should be performed when a woman presents with symptoms that are suggestive of a sexually transmitted infection (STI), when a woman presents with a confirmed STI diagnosis, or when a woman presents with symptoms that are consistent with acute HIV infection.

Use of Dolutegravir in Pregnant Women and Women Who Are Trying to Conceive

The Panel updated the recommendations on the use of DTG in pregnant women and women trying to

conceive based on data available as of August 2019. Restrictions on the use of DTG during the first trimester and in women who are trying to conceive have been removed. DTG is now a *Preferred* ARV drug throughout pregnancy and an *Alternative* ARV drug for women who are trying to conceive. Panel members weighed not only the updated data about DTG-associated risk of infant neural tube defects (NTDs) from Botswana, but also the important lack of comparable data about the risk of NTDs when using DTG in other settings, and what is known about the risk of NTDs and other adverse pregnancy outcomes, such as preterm birth, when using other *Preferred* and *Alternative* ARV drugs and drug combinations.

The following sections of the guidelines now include updated information about the use of DTG:

- [Preconception Counseling and Care for Women of Childbearing Age Living with HIV](#)
- [Teratogenicity](#)
- [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#)
- [Table 4. What to Start: Initial Combination Regimens for Antiretroviral-Naive Pregnant Women](#)
- [Table 5. Situation-Specific Recommendations for Use of Antiretroviral Drugs in Pregnant Women and Nonpregnant Women Who Are Trying to Conceive](#)
- [Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs](#)
- [Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy](#)
- [HIV-2 Infection and Pregnancy](#)
- [Acute HIV Infection](#)
- [Postpartum Follow-Up of Women Living with HIV Infection](#)
- [Dolutegravir](#)
- [Appendix D. Dolutegravir Counseling Guide for Health Care Providers](#)

Reproductive Options for Couples in Which One or Both Partners are Living with HIV

Using antiretroviral therapy (ART) to achieve sustained viral suppression prevents HIV transmission to sexual partners. Given this, the recommendation for couples with differing HIV statuses who are trying to conceive no longer limits intercourse to the period of peak fertility in cases where the partner with HIV has achieved sustained viral suppression. Sexual intercourse without a condom allows for conception with effectively no risk of sexual HIV transmission to the partner without HIV in this situation.

The Panel also reorganized and updated the recommendations that provide guidance when the partner with HIV has not achieved viral suppression or has had inconsistent adherence, or when their viral suppression status is unknown.

A table with information about the efficacy of pre-exposure prophylaxis has been revised and moved to [Appendix C: Clinical Trial Efficacy Data for Daily, Oral Tenofovir Disoproxil Fumarate/Emtricitabine as Pre-Exposure Prophylaxis](#).

Teratogenicity

DTG-related recommendations have been updated (see the updates for Recommendations for Use of Antiretroviral Drugs During Pregnancy below) and a new subsection was added with data about the association between other integrase strand transfer inhibitors (INSTIs) and birth defects. This section also includes recent data about an increased rate of microcephaly in HIV-exposed but uninfected children with *in utero* efavirenz exposure.

Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes

This section was revised and reorganized to focus on data regarding preterm birth, fetal growth restriction, miscarriage, and stillbirth that has been published since 2015. This section also discusses data about

hypertensive disorders of pregnancy and maternal HIV. For historical data related to these topics, please refer to the archived versions of this section.

Recommendations for Use of Antiretroviral Drugs During Pregnancy

The Panel has updated the definitions for the *Preferred* and *Alternative* categories of ARV drugs recommended for use in pregnancy and in women who are trying to conceive.

Based on the available evidence, the Panel now recommends DTG as a **Preferred ARV drug for pregnant women, irrespective of trimester (AII)**, and an **Alternative ARV drug for women who are trying to conceive (AIII)**. The Panel emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV (AIII).

Folic acid is known to prevent NTDs in the general population. All pregnant women and women who might conceive should take at least 400 mcg of folic acid daily (AI). There is no established link between the use of DTG and impaired folate metabolism, nor is there evidence that folate supplementation prevents DTG-associated NTDs.

Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs

Recommendations in this section have been updated in accordance with the updates to Recommendations for Use of Antiretroviral Drugs During Pregnancy, Table 4, and Table 5.

Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy

When pregnant women who are receiving DTG present to care during pregnancy, providers should counsel these women about the risks and benefits of continuing DTG or switching to another ARV regimen (AIII). In most cases, the Panel recommends **continuation** of DTG (AIII).

There are no data about the use of two-drug regimens during pregnancy (e.g., DTG plus lamivudine, DTG plus rilpivirine); women who present to care on one of these regimens should switch regimens or add additional ARV agents to these regimens.

Lack of Viral Suppression

After reviewing a woman's full treatment history and drug resistance test results, a clinician may consider using an INSTI as part of a new regimen for a pregnant woman who is experiencing virologic failure on an ARV regimen that does not contain an INSTI.

Hepatitis B Virus/HIV Coinfection

The Panel's recommendations have been updated to clarify that women who lack hepatitis B virus (HBV) immunity should receive the HBV vaccine.

Hepatitis C Virus/HIV Coinfection

In accordance with the recommendations of the Society for Maternal-Fetal Medicine and the American College of Obstetricians and Gynecologists, the Panel recommends repeat hepatitis C virus (HCV) screening later in pregnancy for women who initially screen negative for HCV but who have persistent or new risk factors for HCV (e.g., new or ongoing injection or intranasal substance use) (AIII).

HIV-2 Infection and Pregnancy

DTG is now recommended for treatment of HIV-2 mono-infection in pregnant women, irrespective of trimester, and in women who are trying to conceive (AIII).

As with HIV-1, the Panel recommends that clinicians consider the possibility of HBV/HIV-2 coinfection when choosing an ARV regimen to treat HIV-2 (AI).

Acute HIV Infection

DTG plus tenofovir disoproxil fumarate (TDF) plus emtricitabine (FTC) is the *Preferred* ARV regimen for pregnant and breastfeeding women with acute HIV, irrespective of trimester (**AII**). Alternatively, raltegravir (RAL) plus TDF plus FTC or a regimen that includes a ritonavir-boosted protease inhibitor can be initiated (**AIII**).

Postpartum Follow-Up of Women Living with HIV

Breastfeeding **is not recommended** for women with HIV, but symptoms related to breast engorgement can be very unpleasant in the days following labor and delivery. The Panel has added a new subsection about lactation inhibition that addresses the management of symptoms related to breast engorgement; this includes use of cabergoline to suppress breast milk production.

Antiretroviral Management of Newborns with Perinatal HIV Exposure or Perinatal HIV

When considering the risk of perinatal HIV transmission and the selection of appropriate ARV drugs for newborns with perinatal HIV exposure, the Panel now defines maternal viral suppression as an HIV RNA level of <50 copies/mL.

A new subsection summarizes information about choosing between empiric HIV therapy and multidrug ARV prophylaxis for newborns with perinatal HIV exposure who are at a high risk of perinatal HIV transmission.

The Panel has also clarified that nevirapine (NVP) can be replaced with lopinavir/ritonavir when infants who are receiving empiric HIV therapy reach a postmenstrual age ≥ 42 weeks and a postnatal age ≥ 14 days; NVP can be replaced with RAL at any age.

Initial Postnatal Management of the Neonate Exposed to HIV

The Panel's recommendation that all newborns who were perinatally exposed to HIV should receive appropriate ARV drugs as soon as possible after delivery (**AI**) is now included in the bulleted list of recommendations for this section.

Appendix B: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy

Table 8: Antiretroviral Drug Use in Pregnant Women with HIV Infection: Pharmacokinetic and Toxicity Data in Human Pregnancy and Recommendations for Use in Pregnancy and other sections in Appendix B have been updated with new data for each drug, including new formulations and fixed-dose combination tablets.

Older ARV drugs that the Panel **does not recommend** for use in pregnant women or women who are trying to conceive because of unacceptable toxicities, inferior virologic efficacy, high pill burden, pharmacologic concerns, and/or limited data about use in pregnancy have been moved to a new section in Appendix B titled Archived Drugs; data about these drugs will no longer be reviewed by the Panel. The drugs that were moved to this section include amprenavir, delavirdine, didanosine, enfuvirtide, fosamprenavir, indinavir, nelfinavir, saquinavir, stavudine, tipranavir, and zalcitabine.